DEC 5 2012

SECTION 5

510(k) SUMMARY

SUMMARY OF SAFETY AND EFFECTIVENESS FOR
Mobile CareGuide™ 2100 Oximeter

Submitter Information

Name:	Reflectance Medical, Inc. (RMI)
Address:	116 Flanders Road, Suite 1000 Westborough, MA 01581 USA
Telephone Number:	508.366.4700
Registration Number:	NA (RMI will apply for registration number following 510(k) clearance, prior to commencement of commercial shipment.)
Contact Person:	Dr. Babs Soller
Telephone Number:	508.366.4700, Ext 223
Fax Number:	508.366.4770
Email:	Babs.Soller@reflectancemedical.com
Date Prepared:	November 20, 2012

Device Name

Device Trade Name:	Mobile CareGuide™ 2100 Oximeter
Device Common Name:	Oximeter
Classification:	Sec 870.2700 Oximeter
Product Code:	MUD
Classification Panel:	Cardiovascular Device Panel

Predicate Devices

Device Trade Name:	CareGuide™ Oximeter
Device Common Name:	Oximeter
Classification:	Sec 870.2700 Oximeter
510(k) Number:	K113656
Product Code:	MUD

Device Description

The Mobile CareGuide 2100 Oximeter sensor uses Near Infrared Spectroscopy (NIRS) to calculate muscle oxygen saturation (SmO_2).

Characteristics	Reflectance Medical Mobile CareGuide 2100 Oximeter
Principle of Operation	NIR spectroscopy
Components	Monitor with reusable sensor and disposable pad
Light Source	LEDs
Parameters Measured	Tissue oxygen saturation (SmO_2)

The Mobile CareGuide 2100 Oximeter is a self-contained, medical oximeter. The sensor contains algorithms that calculate SmO_2 from collected spectra and communicates the current SmO_2 result to a 3rd party display or patient monitor through a proprietary protocol. The Mobile CareGuide 2100 Oximeter reusable sensor contains the optical and electronic elements necessary to collect spectra from skin, fat and muscle. The sensor has a 3m long cord with either a USB connection or CAN connection to the 3rd party display/patient monitor. The sensor contains 6 major components: (1) light sources to illuminate the skin; (2) a spectroscopic detector to analyze the reflected spectra back from the subject; (3) a microprocessor to control the optical components; (4) a microprocessor to perform the spectral analysis and generate the calculated SmO2; (5) one of two different communications components to transmit in CAN or USB format; (6) a battery to power all components. The Mobile CareGuide 2100 Oximeter Ray is a disposable sleeve which isolates the sensor optical elements from the patient's skin.

Indications for Use

The Mobile CareGuide™ 2100 Oximeter is intended for use as an adjunct, non-invasive monitor of the hemoglobin oxygen saturation of microvascular blood in a region of skeletal muscle tissue beneath the sensor. The sensor may be positioned on pigmented skin. The Mobile CareGuide 2100 Oximeter is intended to allow for display of SmO2 data on a third party device, which would interface with the Mobile CareGuide 2100 Oximeter via USB or CAN connection. The Mobile CareGuide 2100 Oximeter is intended for prescriptive use (Rx only) by a trained healthcare professional in a hospital. The Mobile CareGuide 2100 Oximeter provides output of the most recent value of SmO2, as well as operational device information. The Mobile CareGuide 2100 Oximeter should not be used as the sole basis for diagnosis or therapy. Note: The prospective clinical value of data from the Mobile CareGuide 2100 Oximeter has not been demonstrated in disease states.

Rationale for Substantial Equivalence

The Mobile CareGuide™ 2100 Oximeter is substantially equivalent to the Reflectance Medical CareGuide™ Oximeter (K113656).

The Mobile CareGuide 2100 Oximeter is substantially equivalent to the predicate by intended use and design.

- The principle of operation of the Mobile CareGuide 2100 Oximeter is identical to that of the predicate device. They use the exact same NIR Spectroscopy to measure tissue oxygen saturation. The same software quantitative algorithm is used in both devices.
- The Mobile CareGuide 2100 Oximeter is equivalent to the predicates in components. Both devices use the exact same optical board (light sources, spectrometer and microprocessor).
- The Mobile CareGuide 2100 Oximeter has the identical underlying LED light source as the predicate, with the exact same ranges of wavelength (700-900 nm) and number of wavelengths.
- The Mobile CareGuide 2100 Oximeter produces the same numeric data to be displayed on a 3rd party device as the predicate device.
- The Intended Use is identical to the predicate. Both are intended for use as oximeters, to measure tissue oxygen saturation.

Summary of Safety and Effectiveness Data

Testing demonstrates that the Mobile CareGuide 2100 Oximeter is a safe and effective oximeter meeting all relevant consensus and FDA recognized standards. The test results in this submission demonstrate that the Mobile CareGuide 2100 Oximeter meets the expected performance requirements for an Oximeter, and is therefore equivalent to the predicate relative to safety and mechanical properties. The accuracy and safety of the Mobile CareGuide 2100 Oximeter is the same as the predicate device.

Conclusion

The Mobile CareGuide 2100 Oximeter is equivalent to predicate device in terms of technology (NIR Spectroscopy) and intended use. The Mobile CareGuide 2100 Oximeter, with its embedded microprocessor and supporting components, does not raise new questions of safety or effectiveness, as compared to the predicate. Therefore, the Mobile CareGuide 2100 Oximeter is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

DEC 5 2012

Reflectance Medical, Inc.
c/o Nandini Murthy
116 Flanders Rd, Suite 1000
Westborough, MA 01581

Re: K122645
Trade/Device Name: Mobile CareGuide 2100 Oximeter
Regulation Number: 21 CFR §870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: MUD
Dated: November 21, 2012
Received: November 27, 2012

Dear Ms. Murthy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mitchell J. Shein
2012.12.05 15:14:32
-05'00'

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

Indications for Use

510(k) Number (if known): K122645

Device Name: ___Mobile CareGuide™ 2100 Oximeter___

Indications for Use:

The Mobile CareGuide™ 2100 Oximeter is intended for use as an adjunct, non-invasive monitor of the hemoglobin oxygen saturation of microvascular blood in a region of skeletal muscle tissue beneath the sensor. The sensor may be positioned on pigmented skin. The Mobile CareGuide 2100 Oximeter is intended to allow for display of SmO2 data on a third party device, which would interface with the Mobile CareGuide 2100 Oximeter via USB or CAN connection. The Mobile CareGuide 2100 Oximeter is intended for prescriptive use (Rx only) by a trained healthcare professional in a hospital. The Mobile CareGuide 2100 Oximeter provides output of the most recent value of SmO2, as well as operational device information. The Mobile CareGuide 2100 Oximeter should not be used as the sole basis for diagnosis or therapy. Note: The prospective clinical value of data from the Mobile CareGuide 2100 Oximeter has not been demonstrated in disease states.

Prescription Use __X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page __ of ___

Mitchell J. Shein
2012.12.05
15:13:33 -05'00'

Bram Zuckerman, M.D.